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Food and Drug Administration

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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting and Recordkeeping Requirements and Availability of Sample Electronic Products for Manufacturers and Distributors of Electronic Products (OMB Control Number 0910-0025)—Extension

Under sections 532 through 542 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360ii through 360ss), FDA has the responsibility to protect the public from unnecessary exposure from radiation from electronic products. The regulations issued under these authorities are listed in 21 CFR chapter I, subchapter J. Specifically, subchapter A regulations, 21 CFR 5.10(a)(3), 5.25(b), 5.35(a)(4), and 5.600 through 5.606, delegate administrative authorities to FDA.

Section 532 of the act directs the Secretary of the Department of Health and Human Services (the Secretary) to establish and carry out an electronic product radiation control program, including the development, issuance, and administration of performance standards to control the emission of electronic product radiation from electronic products. The program is designed to protect the public health and safety from electronic radiation, and the act authorizes the Secretary to procure (by negotiation or otherwise) electronic products for research and testing purposes and to sell or otherwise dispose of such products.

Section 534(g) of the act directs the Secretary to review and evaluate industry testing programs on a continuing basis; and sections 535(e) and (f) of the act direct the Secretary to immediately notify manufacturers of, and ensure correction of, radiation defects or noncompliances with performance standards.

Section 537(b) of the act contains the authority to establish and maintain records (including testing records), make reports, and provide information to determine whether the manufacturer has acted in compliance.

Parts 1002 through 1010 (21 CFR parts 1002 through 1010) specify reports to be provided by manufacturers and distributors to FDA and records to be maintained in the event of an investigation of a safety concern or a product recall.

FDA conducts laboratory compliance testing of products covered by regulations for product standards in parts 1020, 1030, 1040, and 1050 (21 CFR parts 1020, 1030, 1040, and 1050).

FDA details product-specific performance standards that specify information to be supplied with the product or require specific reports. The information collections are either specifically called for in the act or were developed to aid the agency in performing its obligations under the act. The data reported to FDA and the records maintained are used by FDA and the industry to make decisions and take actions that protect the public from radiation hazards presented by electronic products. This information refers to the identification of, location of, operational characteristics of, quality assurance programs for, and problem identification and correction of electronic products. The data provided to users and others are intended to encourage actions to reduce or eliminate radiation exposures.

FDA uses the following forms to aid respondents in the submission of information for this information collection: (1) Form FDA 2767, "Notice of Availability of Sample Electronic Product;" (2) Form FDA 2877, "Declaration for Imported Electronic Products Subject to Radiation Control Standards," and

(3) Form FDA 3147, "Application for a Variance From 21 CFR 1040.11(c) for a Laser Light Show, Display, or Device."

The most likely respondents to this information collection will be electronic product and x ray manufacturers, importers, and assemblers.

In the **Federal Register** of June 12, 2003 (68 FR 35231), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received two comments on the FDA radiation program paperwork burden (under OMB control number 0910-0025). One comment pertained to the information collection. It stated that the Occupational Safety and Health Administration and the Department of Health and Human Services (DHHS) already have radiation standards and that government paperwork on radiation emissions is of dubious value until more research is conducted, particularly on nonthermal effects of microwave/radiofrequency radiation. FDA is the agency of DHHS that is responsible for radiation safety standards for electronic products. Industry paperwork on radiation safety provides the agency with critical information on radiation controls, such as safety interlocks, timers, warning labels, etc., and on radiation emissions that are compared to known bioeffects hazards, whether specified in mandatory FDA standards or more recent consensus standards. Specifically, information provided to FDA on microwave radiation is compared to levels known to cause thermal injuries.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1002.3		10	1	10	12	120
1002.10 and 1010.3		540	1.6	850	24	20,400
1002.11		1,000	1.5	1,500	0.5	750
1002.12		150	1	150	5	750

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹—Continued

21 CFR Section	Form No	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
1002.13 annual		900	1	900	26	23,400
1002.13 quarterly		250	2 4	600	0 5	300
1002.20		40	1	40	2	80
1002.50(a) and 1002.51		10	1.5	15	1	15
	FDA 2877	600	32	19,200	0 2	3,840
1010.2		1	1	1	5	5
1010.4(b)		1	1	1	120	120
1010.5 and 1010.13		3	1	3	22	66
	FDA 2767	145	11.03	1,600	0.09	144
1020.20(c)(4)		1	1	1	1	1
1020.30(d), (d)(1), and (d)(2)	FDA 2579	2,345	8.96	21,000	0.30	6,300
1020.30(g)		200	1.33	265	35	9,275
1020.30(h)(1) through (h)(4), 1020.32(a)(1) and (g)		200	1.33	265	35	9,275
1020.32(g) and 1020.33(c), (d), (g)(4), (j)(1), and (j)(2)		9	1	9	40	360
1020.40(c)(9)(i) and (c)(9)(ii)		8	1	8	40	320
1030.10(c)(4)		41	1.61	66	20	1,320
1030.10(c)(5)(i) through (c)(5)(iv)		41	1.61	66	20	1,320
1030.10(c)(6)(iii) and (c)(6)(iv)		1	1	1	1	1
1040.10(a)(3)(i)		83	1	83	3	249
1040.10(h)(1)(i) through (h)(1)(vi)		805	1	805	8	6,440
1040.10(h)(2)(i) and (h)(2)(ii)		100	1	100	8	800
1040.11(a)(2)		190	1	190	10	1,900
1040.11(c)	FDA 3147	53	2.2	115	0.5	58
1040.20 (d), (e)(1), and (e)(2)		110	1	110	10	1,100
1040.30(c)(1)		1	1	1	1	1
1040.30(c)(2)		7	1	7	1	7
1050.10(f)(1) through (f)(2)(iii)		10	1	10	56	560
Total Annual Reporting Burden						89,278

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

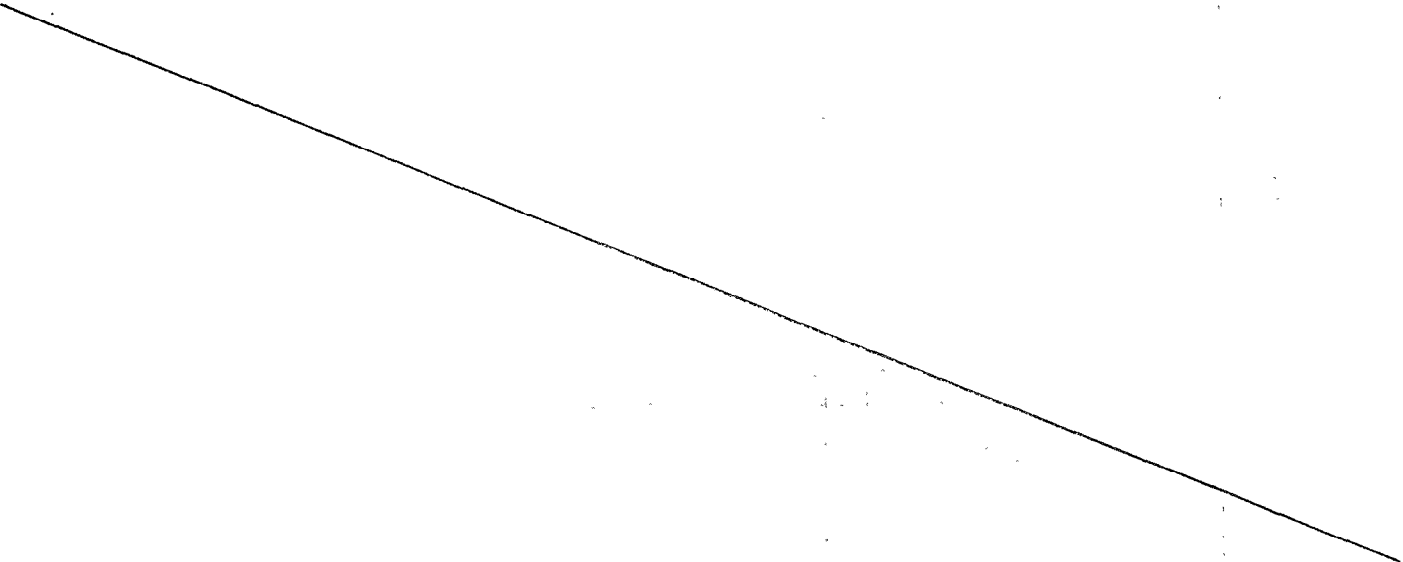
21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
1002.30 and 1002.31(a)	1,150	1,655.5	1,903,825	198.7	228,505
1002.40 and 1002.41	2,950	49.2	145,140	2.4	7,080
1020.30(g)(2)	22	1	22	0.5	11
1040.10(a)(3)(ii)	83	1	83	1.0	83
Totals					235,679

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates were derived by consultation with FDA and industry personnel and actual data collected from industry over the past 3 years. An

evaluation of the type and scope of information requested was also used to derive some time estimates. For example, disclosure information primarily requires time only to update and maintain existing manuals. Initial development of manuals has been performed except for new firms entering the industry. When information is generally provided to users, assemblers, or dealers in the same manual, they have been grouped together in table 1 of this document.

The following information collection requirements are not subject to review by OMB because they do not constitute a "collection of information" under the PRA: Sections 1002.31(c); 1003.10(a), (b), and (c); 1003.11(a)(3) and (b); 1003.20(a) through (h); 1003.21(a) through (d); 1003.22(a) and (b); 1003.30(a) and (b); 1003.31(a) and (b); 1004.2(a) through (i); 1004.3(a) through (i); 1004.4(a) through (h); and 1005.21(a) through (c). These requirements "apply to the collection of information during the conduct of general investigations or audits" (5 CFR 1320.4(b)). According to 5 CFR 1320.3(c)(2), the following labeling requirements are also not subject to review under the PRA because they are a public disclosure of information originally supplied



by the Federal Government to the recipient for the purpose of disclosure to the public: Sections 1020.10(c)(4), 1030.10(c)(6), 1040.10(g), 1040.30(c)(1), and 1050.10(d)(1).

Dated: 9-30-03

September 30, 2003.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

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